

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANTARUS, INC., and THE CURATORS
OF THE UNIVERSITY OF MISSOURI,)
)

Plaintiffs,)

v.)

PAR PHARMACEUTICAL, INC.,)

Defendant.)

C.A. No. 07-551-GMS
(CONSOLIDATED)

REDACTED
PUBLIC VERSION

**PAR PHARMACEUTICAL, INC.'S MOTION IN LIMINE TO EXCLUDE
ANY TESTIMONY OF GILBERT BANKER REBUTTING
THE ISSUES OF ANTICIPATION AND OBVIOUSNESS**

I. INTRODUCTION

Defendant Par Pharmaceutical, Inc. moves in limine to exclude the opinion testimony of Defendants Santarus, Inc.'s and The Curators of the University of Missouri's (collectively, "Plaintiffs") technical expert, Gilbert S. Banker, regarding the alleged validity of United States Patent Nos. 6,489,346, 6,645,988, 6,780,882, 6,699,885, and 7,399,772 (the "Patents-in-Suit"). Specifically, Dr. Banker provided no substantive analysis to rebut the detailed anticipation and obviousness arguments set forth by Par's formulation expert, Dr. Loyd Allen. Dr. Banker's rebuttal to Dr. Allen's opening expert report merely contains an unsubstantiated statement that Par's experts failed to establish that the asserted claims are invalid. He provides no bases and reasons (the "how" and "why") supporting his conclusion. Accordingly, the Court should preclude Dr. Banker's trial testimony to the extent it relates to rebutting obviousness and anticipation.

II. BACKGROUND

Plaintiffs have asserted over 110 patent claims against Par. Par's formulation expert, Dr. Allen, opined in his expert reports that each of these claims is invalid under, among other things, 35 U.S.C. §§ 102 & 103. Dr. Allen submitted expert reports detailing the bases and reasons for his opinions. Specifically, Dr. Allen submitted a thirty-one page opening expert report along with 366 pages of detailed claim charts supporting his opinions on anticipation and obviousness of the asserted claims. In his response, Dr. Banker failed to address the claim charts submitted by Dr. Allen. *See* Second Expert Report of Dr. Gilbert S. Banker at p. 2 ("Second Report"). Dr. Banker's Second Report is completely devoid of any supported opinions regarding whether the patents-in-suit are anticipated or obvious. Dr. Banker merely provided a one-line, conclusory statement that it was non-obvious. Nor was this conclusory statement linked to any particular asserted patent, much less any specific patent claim. When asked about anticipation and obviousness at his deposition,

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III. ARGUMENT

A. Any Dr. Banker Testimony Should Be Excluded Pursuant to Rules 26(a)(2)(B) and 37(c)(1).

Any Dr. Banker testimony rebutting anticipation and obviousness should be excluded. It is well-settled that an expert may not present opinions at trial that were not properly and timely disclosed pursuant to Federal Rules of Civil Procedure 26(a)(2)(B). That rule requires an expert witness to submit a written report that, *inter alia*, "must contain a complete statement of all opinions the witness will express and the basis and reasons for them." Rule 37(c)(1), in turn, provides that "[i]f a party fails to provide information . . . as required by Rule 26(a) . . . the party

¹ Dr. Banker thus acknowledges that his testimony on these areas is not necessary but instead is cumulative.

is not allowed to use that information . . . to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless.” To ensure compliance with the disclosure requirement imposed by Rule 26(a)(2)(B), courts are entrusted with broad discretion in determining whether exclusion of proffered testimony under Rule 37 is appropriate. *See, e.g., AstraZeneca LP v. Tap Pharm. Prods. Inc.*, 444 F. Supp. 2d 278, 286 (D. Del. 2006).

Here, Dr. Banker did not rebut that the asserted claims are anticipated and/or obvious. Dr. Banker merely stated that Par’s experts failed to establish that the asserted claims are invalid but failed to provide the bases and reasons for this statement. Moreover, Dr. Banker did not even discuss anticipation in his Second Report, much less provide which elements of the prior art are absent from the asserted claims.

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Dr. Banker then discussed alleged obstacles in drug dosage formulation, but he did not address any of the prior art discussed by Dr. Allen.

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Therefore, Dr. Banker’s failure (or conclusory and unsupported statements at best) to rebut anticipation and obviousness of the asserted claims should preclude him from offering testimony at trial about the same.

B. Dr. Banker’s Testimony Should be Excluded Pursuant to Rule 702 and Daubert.

Dr. Banker’s failure to rebut the anticipation and obviousness showings do not satisfy the requirements under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589-90 (1993). Rule 702 requires that an expert opinion be “based upon sufficient

facts or data” as well as the “product of reliable principles and methods” that are “reliably” applied to the facts of the case. Reliable expert opinion evidence “must be based on the methods and procedures of science rather than on subjective belief or unsupported speculation.” *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994); *see also Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 157 (1999) (“nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert”) (citation omitted). Both *Daubert* and Rule 702 charge the trial judge with a “gatekeeper” function to ensure the reliability and relevance of the expert testimony admitted into evidence. *Kumho*, 526 U.S. at 149.

Allowing Dr. Banker to testify at trial that the asserted patents are not anticipated or obvious—when he offered no such opinions or conclusory and unsupported statements at best—would contravene the requirements of Rule 702 and *Daubert*. As discussed above, a reliable expert opinion is not one based on subjective belief or unsupported speculation, which is exactly what Dr. Banker provides in his expert report. Further, Dr. Banker’s opinions are not a “product of reliable principles and methods” that are “reliably” applied to the facts of the case because Dr. Banker did not conduct an analysis for each of the asserted claims to rebut anticipation and obviousness. Accordingly, Dr. Banker’s expert testimony on these issues should be excluded.

C. Plaintiffs’ Failure to Comply with Rule 26(a)(2)(B), Rule 702, and *Daubert* is Not Substantially Justified and Prejudices Par.

Plaintiffs cannot justify their failure to provide a complete expert report that complies with Rule 26(a)(2)(B), Rule 702, and *Daubert*. Dr. Banker had access to all of the information needed to produce a complete report. The failure to provide a complete expert report cannot be substantially justified, and has prejudiced Par. Specifically, Dr. Banker’s expert report does not provide adequate information for Par to effectively evaluate or challenge his opinions at trial.

Given Plaintiffs' lack of a substantial justification for failing to provide an expert report that complies with Rule 26(a), Rule 702, and *Daubert* and given the prejudice to Par as a result, the Court should preclude Plaintiffs from offering expert testimony from Dr. Banker to rebut Par's anticipation and obviousness showing of the asserted patent claims.

IV. CONCLUSION

Par respectfully asks that the Court exclude any testimony from Dr. Banker at trial regarding validity of the patents-in-suit for the reasons stated above.

Of Counsel:
Janine A. Carlan
Aziz Burgy
Timothy W. Bucknell
Joshua T. Morris
Arent Fox LLP
1050 Connecticut Ave., N.W.
Washington, D.C., 20036
(202) 857-6000

Dated: May 13, 2009

/s/ Steven J. Fineman
Frederick L. Cottrell, III (#2555)
Cottrell@rlf.com
Steven J. Fineman (#4025)
Fineman@rlf.com
Richards, Layton & Finger P.A.
One Rodney Square
P.O. Box 551
Wilmington, DE 19899
(302) 651-7700
Attorneys for Par Pharmaceutical, Inc.

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Defendant.)	

ORDER

WHEREAS, the Court having considered Defendant Par Pharmaceutical, Inc.'s Motion to Exclude Any Testimony of Dr. Gilbert S. Banker Rebutting the Issues of Anticipation and Obviousness (the "Motion");

WHEREAS, the Court having considered the briefs and arguments in support of and in opposition to the Motion;

IT IS HEREBY ORDERED this _____ day of _____, 2009 that the Motion is GRANTED.

Chief United States District Judge

**CERTIFICATION PURSUANT TO
DISTRICT OF DELAWARE LOCAL RULE 7.1.1.**

Counsel for Defendant has consulted with counsel for Plaintiffs pursuant to District of Delaware Local Rule 7.1.1 and has determined that Plaintiffs are opposed to the relief sought in the attached motion.

Dated: May 13, 2009

/s/ Steven J. Fineman
Steven J. Fineman (#4025)

EXHIBIT A

REDACTED

IN ITS

ENTIRETY

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE**

CERTIFICATE OF SERVICE

I hereby certify that on May 13, 2009, I electronically filed the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filing(s) and I also certify that on May 13, 2009, I caused to be served true and correct copies of the foregoing on the following counsel of record in the manner indicated:

BY ELECTRONIC MAIL

Jack B. Blumenfeld, Esquire
James Walter Parrett, Jr., Esquire
Morris, Nichols, Arsht & Tunnell LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347

/s/ Steven J. Fineman

Steven J. Fineman (#4025)
fineman@rlf.com

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE**

CERTIFICATE OF SERVICE

I hereby certify that on May 18, 2009, I electronically filed the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filing(s) and I also certify that on May 18, 2009, I caused to be served true and correct copies of the foregoing on the following counsel of record in the manner indicated:

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